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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,809	01/29/2004	Paul J. Dominowski	PC25496A	6275

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,809	DOMINOWSKI ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *14-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/04,6/5/06,4/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-13, in the reply filed on 11/1/06 is acknowledged. The traversal is on the ground(s) that non-elected claims 29-34 should be in Group III (even though they depend from claim 14) because they relate to a combination vaccine. They also argue that it would not place a serious burden on the Examiner to examine all of the Groups together because the Groups are directed to the same class. This is not found persuasive because Class 424 contains over 500 subclasses, each drawn to divergent and independent subject matter. The inventions of I-III are in different *subclasses* and are distinct and independent inventions. Inventions I, II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as a vaccine for *protecting* against *B.bronchiseptica*. The vaccines of Groups II and III are multivalent vaccines which require many additionally components that are structurally different and the methods are for producing an immune response against multiple canine pathogens, not protecting against *B.bronchiseptica*. The vaccine of Group I comprises solely the p68 antigen and an adjuvant for protection against *B.bronchispetica*, whereas the vaccine of Group II is a multivalent vaccines which is designed to raise an immune response against multiple canine pathogens. The vaccine requires numerous antigens not present in the vaccine of Group I, e.g., an attenuated strain of canine distemper

(CD) virus, an attenuated strain of canine adenovirus type 2 (CAV-2), an attenuated strain of canine parainfluenza (CPI) virus and an attenuated strain of canine parvovirus (CPV); an inactivated whole or partial cell preparation of a strain of canine coronavirus (CCV). The prior art teaches that multivalent vaccines are unpredictable and it would not have been obvious to merely add multiple different antigens to the vaccine of Group I. These vaccines are completely different products. The vaccines of Groups II and III also comprise different components which raise completely different immune responses. See MPEP § 806.05(d). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search required for the Groups is not coextensive, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 14-51 are withdrawn from consideration because they are drawn to a non-elected invention.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

On 2/12/04, the following message was generated by the Sequence Compliance specialists: "CRF DOES NOT MATCH APPLICATION SPECIFICATION -- APPLICANT MUST CORRECT". Accordingly, Applicant must fix these compliance issues. A statement under 37 CFR 1,821(f) stating that the original CRF and sequence listing are the same must be provided.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821-25. Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 C.F.R. 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 4, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al (WO 92/17587).

Charles et al teach the isolation of the native P68 antigen of Bordetella bronchispetica. Pages 1-6 teach the recombinant production of this polypeptide. Page 6, line 7, specifically teaches that E.coli may be used as a host cell. Page 7 teaches the use of this protein in a vaccine composition. Page 7, lines 30-34 teach that an adjuvant may be added to the vaccine composition. Aluminum hydroxide is specifically recited in line 34. The reference specifically recites that the vaccine is for veterinary use. Page 1, lines 5-6, teach that B.bronchispetica is a bacterial pathogen associated with respiratory disease in animals. The amino acid sequence taught by the reference is identical to that which is recited in SEQ ID NO:1. Although Charles et al do not specficially recite that the vaccine may be used to protect dogs against B.bronchispetica, The term "vaccine,

effective to protect dogs against Bordetella bronchispetica" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Charles et al is structurally identical to that recited in claims 1-5 and 9, and therefore it would be capable of performing the intended use.

5. Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Montaraz et al (Infection and Immunity, 1985, 47: 744-751).

Montaraz et al teach the isolation of the native P68 antigen of Bordetella bronchispetica. Active immunization using this antigen in incomplete Freund adjuvant or Alhydrogel is taught, see top of page 758, column 1. The reference teaches that B.bronchispetica is a bacterial pathogen associated with respiratory disease in animals. See page 744, column 1. Although Montaraz et al do not specficially recite that the vaccine may be used to protect dogs against B.bronchispetica, The term "vaccine, effective to protect dogs against Bordetella bronchispetica" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Montaraz et al is structurally identical to that recited in claims 1-5 and 9, and therefore it would be capable of performing the intended use. Although Montaraz et al

do not specifically recite the amino acid sequence of their P68 antigen, it would inherently be that set forth in Applicant's SEQ ID NO: 1, given the source, activity, and size, absent specific evidence to the contrary. The amino acid sequence of a known protein is an inherent property and the later elucidation of the amino acid sequence of an already known protein does not impart novelty. Additionally, claim 2 is a product-by-process claim. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). The product claimed is of identical size, has identical function and was obtained from an identical source, accordingly it would be expected to be the same.

6. Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Novonty et al (Infection and Immunity, 1985, 47: 744-751).

Novonty et al teach the isolation of the native P68 antigen of Bordetella bronchispetica. Active immunization using this antigen in oil or mineral adjuvant is taught, see page 192, column 2, 2nd paragraph above the "Results". The reference teaches that B.bronchispetica is a bacterial pathogen associated with respiratory

disease in animals. See page 190, column 1. Although Novonty et al do not specficially recite that the vaccine may be used to protect dogs against B.bronchispetica, The term "vaccine, effective to protect dogs against Bordetella bronchispetica" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The vaccine composition recited by Novonty et al is structurally identical to that recited in claims 1-5, and therefore it would be capable of performing the intended use. Although Novotny et al do not specifically recite the amino acid sequence of their P68 antigen, it would inherently be that set forth in Applicant's SEQ ID NO: 1, given the source, activity, and size, absent specific evidence to the contrary. The amino acid sequence of a known protein is an inherent property and the later elucidation of the amino acid sequence of an already known protein does not impart novelty. Additionally, claim 2 is a product-by-process claim. "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the

prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983). The product claimed is of identical size, has identical function and was obtained from an identical source, accordingly it would be expected to be the same.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Charles et al (WO 92/17587), Montaraz et al (Infection and Immunity, 1985, 47: 744-751) or by Novonty et al (Infection and Immunity, 1985, 47: 744-751) in view of Azko et al (EP 0 535 740 A1) and Garcon et al (WO 96/33739) and further in view of Acree et al (US Patent No. 4,567,042).

The teachings of Charles, Montaraz and Novonty et al are set forth above. Although they teach vaccines comprising the P68 antigen from B.bronchiseptica and an adjuvant. They do not specifically teach that the adjuvant may comprise saponin and a surfactant, more particularly Quil A and cholesterol, nor do the primary references teach a method of protecting dogs against B.bronchiseptica comprising administering to a dog said vaccine.

As one of ordinary skill in the art can see from the primary references, B.bronchiseptica p68 antigen is a well known protein whose relevance in vaccination and protective properties are well documented in the prior art. Azko specifically teaches

that dogs are sensitive to infection by B.bronchiseptica and that B.bronchiseptica is the primary etiological agent in infectious canine tracheobronchitis (kennel cough). See last full paragraph at the bottom of page 2. It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen. The vaccines taught in the claims would appear to work as well in canines, as in other animals, e.g., pigs, rabbits, guinea pigs, mice, etc., absent specific evidence to the contrary. Azko specifically teaches the use of saponin as a possible adjuvant for B.bronchiseptica vaccines. See page 3, lines 42-44 and 56-57). Garcon et al teches the use of saponins and cholesterol as an adjuvant and lists antigens from B.bronchiseptica as possible applications for the saponin-cholesterol adjuvant (page 3, lines 19-20). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the adjuvant used in any of the primary references with saponin, such as Quil A, and cholesterol since the prior art (Azko and Garcon) teach these adjuvants worked well in vaccines comprising B.bronchiseptica antigens.

Prior Art Made of Record, not relied on:

A) Novotny et al Infect. Immun. Oct. 1985, 50(1): 199-206. Novotny et al. teach the isolation of a 68K outer membrane protein from B.bronchispetica with adenylate cyclase activity. However, they do not specifically recite that an adjuvant was used.

B) Kobisch et al Infect. Immun. Feb. 1990, 58(2): 352-357. Novotny et al. teach the isolation of a 68K outer membrane protein from B.bronchispetica with adenylate cyclase activity. However, they do not specifically recite that an adjuvant was used.

9. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

11/20/06

Jennifer Graser
Primary Examiner
Art Unit 1645